OCT 31 2002

K022663

Premarket Notification 510(k) **KERADEC**

5. 510 (k) Summary

Submitter of 510(k): Wieland Dental + Technik GmbH & Co. KG
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Date of Summary: 2002-07-30

Trade name: KERADEC

Classification name: Alloy, gold based, for clinical use
Product code: EJT
C.D.R section: 872.3060
Classification: Class II

Legally marketed equivalent device: Blendgold Special
510(k) number: K 851872

Device description

KERADEC is a fuse-on gold paste, which can be used by dental technicians to fabricate dental appliances for patients. It consists of spherical gold particles and an organic liquid.

KERADEC is intended for gold coating of white dental alloys. It can be used for gold coating of white metal surfaces in cervical areas, elimination of casting cavities, gold coating of occlusal surface and inlay imitations.

The use of KERADEC improves the color reproduction of ceramics on white porcelain-fused-to-metal alloys. It optimizes the color of white dental alloys and reduces oxidation of these alloys. It does not improve the metal to ceramic bond.

For applying, KERADEC has to be brushed onto the surface of the alloy and, after drying, it has to be fired in a ceramic furnace (820°C). In the course of these heat treatments, the organic liquid will completely vaporize and the gold will form a very thin layer of pure gold (99.99%), which is partly diffused into the surface of the alloy.

KERADEC is highly corrosion resistant. It meats the essential requirements of the European directive 93/42/ECC concerning medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2002

Dr. Gerhard Polzer
Director, Regulatory Affairs
Wieland Dental + Technik GmbH & Co. KG
Schwenninger Straße 13
D-75179 Pforzheim
GERMANY

Re: K022663
Trade/Device Name: KERADEC
Regulation Number: 872.3060
Regulation Name: Gold-Based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Code: EJT
Dated: August 5, 2002
Received: August 9, 2002

Dear Dr. Polzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4513. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022663

Device Name: **KERADEC**

Indications For Use:

KERADEC is a fuse-on gold paste, which can be used by dental technicians to manufacture dental appliances for patients.

It is intended for gold coating of white metal surfaces in cervical areas, elimination of casting cavities, gold coating of occlusal surfaces and inlay imitations.

In addition, it can be used within the AGC electroforming technique to manufacture AGC Bridges with the sintering procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K022663

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)